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American Type Culture Collection (ATCC)
Vice President: Business Development

- Responsible for acquisitions, licensing, intellectual property policy, and research collaborations
- Responsible for development of international distribution
- Responsible for creation and operations of BioDominion a for-profit subsidiary of the ATCC; President and member of the Board of Directors of BioDominion

Genetic Therapy Inc. (A Novartis Company) 1997-1999

Vice President: Business Development

- Responsible for licensing negotiations, evaluation of potential acquisitions, and business and intellectual property aspects of research collaborations with non-profit research institutions and corporations. Coordinate Genetic Therapy Inc. (GTI) business development activities with other functions within Novartis Pharmaceuticals.
- Oversee on-going research collaborations with laboratories at the NIH, in universities, and with corporate partners.
- Review and sign all agreements involving confidential information, material transfers, and consulting, clinical development or other services.
- Actively search out product and technology licensing opportunities to complement internal GTI and Novartis research.

Gen-Probe Incorporated 1995-1997

Vice President: Business Development

- Negotiated a comprehensive agreement between Gen-Probe and a major French company involving technology licensing, joint research and development, co-marketing, and international distribution.
- Negotiated an agreement between Gen-Probe and a major European company related to conflicting patent rights, thereby avoiding costly and damaging litigation.
- Responsible for the evaluation and licensing of technology, corporate acquisitions and partnerships, and other business arrangements with other companies or with non-profit institutions.
- Officer of the company and member of the Global Coordinating Group: Diagnostic Business for Chugai Pharmaceuticals Ltd. and the Gen-Probe New Product Planning Committee. (Chugai Pharmaceuticals owns Gen-Probe). Collaborated with and supported corporate development efforts at Chugai Biopharmaceuticals in San Diego.

Life Technologies Inc. 1978-1995

Director: Intellectual Property and Technology Acquisition

1989- to 1995

- Managed the prosecution and enforcement of patents and trademarks, and intellectual property litigation. Approved the exchange of proprietary research materials and confidential scientific information. Evaluated patent risks associated with proposed research projects or product introductions, and acquired necessary rights through licensing. Managed drafting and prosecution of more than 60 patent applications resulting in the issuance of more than 45 US Patents. Inventor on 12 issued US Patents (listed below).
- Negotiated more than 40 licenses with universities, the federal government, individual scientists, and private companies. Supported corporate development in the evaluation of product line and business acquisitions and license administration.
- Identified an opportunity for LTI to enter the custom oligonucleotide business through the formation of a partnership with Protogene Laboratories Inc. Worked with corporate development to frame an exclusive marketing agreement with Protogene, negotiated terms under which Life Technologies made its initial investment in Protogene. Member of the Board of Directors of Protogene Laboratories Inc. Managed the purchase by Life Technologies of this business from Protogene's founders.
- Directed a research group of 9 scientists (6 Ph.D. 3 MS.) in the area of DNA amplification and manipulation, especially long-range PCR. Developed LTI's first product for long PCR "Elongase" as well as a ready to use formulation of Taq DNA polymerase. Directed the introduction of automated enzymatic assays in production and quality control.

Director: Intellectual Property

Research Director: Molecular Probe Technology 1987-1989

- Management of patents and confidential information as above.
- Directed a research group of developing sensitive non-radioactive assays for DNA or RNA sequences of clinical importance. This work was terminated with the sale to Digene Inc. of LTI's Molecular Diagnostics Division. Two assay methods were developed; one was patented and licensed to another company, the other was transferred to Digene as know-how and became the basis for diagnostic tests currently sold by Digene.

Research Director: Molecular Virology 1980--1987

- Directed a nine member research group developing hybridization based assays for hepatitis B virus, cytomegalovirus, and human papillomavirus. Rights to major aspects of this research were licensed to Toray Ltd. and know-how was transferred to Toray scientists in Japan.

New Product Development Manager 1978-1980

- Developed, marketed, and occasionally manufactured new nucleic acid modifying enzymes to expand the company's product line. Initiated a research program, which evolved into the company's diagnostics business in DNA probes.

Research Assistant and Instructor: Mass. Inst. of Tech. 1971-1973

- Set up a new laboratory at MIT for Dr. Irving M. London in the area of in vitro protein synthesis and taught first year biology laboratory to MIT pre-med undergraduates.

Education:

- Columbia University-Major in Biology 1966- 1970
- Massachusetts Institute of Technology-Biology 1970-1971; 1973-1978
- Patent Bar Review/Registered U.S. Patent Agent No. 32,396 1986
- Dexter Corporation Management course at Hartford Graduate Center

- European Patent Practice and Complete Chemical Practice by Patent Resources Group
- Litigation Risk Management

Professional Associations:

- Association of University Technology Managers
- Licensing Executives Society
- American Society of Microbiology

Presentations:

- International Symposium on Viral Hepatitis, 1981
- Molecular Biology of Hepatitis Viruses, Cold Spring Harbor Laboratory, 1987
- International Congress on Rapid Methods and Automation in Microbiology and Immunology, Berlin 1984
- San Diego Conference on Nucleic Acids, 1990
- Commercializing Biomedical Technologies, Boston, 1991
- Workshops on Exchange of Proprietary Biological Materials for the Association of University Technology Managers, 1992 and 1993
- IBC Conference on Gene Therapy; The Royal Society, London, 1998
- 18th Annual ATCC Patent and Licensing Forum, Co-Chairman, 2000
- AUTM Advanced Licensing Course 2000

Publications:

Bonner, J., Berninger, M., and Pardue, M. L. (1977) Transcription of Polytene Chromosomes and the Mitochondrial Genome of *Drosophila Melanogaster*. Cold Spring Harbor Symposium on Quantitative Biology, 2:803-814.

Berninger, M., Cech, T., Fostel, J.M., Potter, D., Scott, M., and Pardue, M. L. (1979) The Structure and Function of Mitochondrial DNA of *Drosophila Melanogaster*. Alfred Benzon Symposium, Specific Eukaryotic Genes. (J. Engberg, H. Klenow and V. Leick eds.) Munksgaard, Copenhagen 13: 229-243.

Potter, D., Fostel, J.M., Berninger, M., Pardue, M. L., and Cech, T.R. (1980) DNA-Protein Interactions in the *Drosophila Melanogaster* Mitochondrial Genome as Deduced from Trimethylpsoralen Crosslinking Patterns. Proc. Nat. Acad. Sci. U.S. 77: 4118-4122.

Berninger, M., Hammer, M. L., Hoyer, B., and Gerin, J.L. (1982) An Assay for the Detection of the DNA Genome of Hepatitis B. Virus in Serum. J. Med. Virol. 9: 57-68.

Vladutiu, A. O., Pudlad, K.A., Hammer, M. L., Berninger, M., and Leibowitz, A. I. (1982) Effect of Human Fibroblast Interferon (INF-Beta) on Hepatitis B Virus DNA in Serum. Biomed. Pharmacother. 3: 162-164.

Fields, H.A., Berninger, M., Nathe, N., Davis, D.L., Hammer, M.L., Margoles, H.S., McCaustland, K.A., Wheeler, C.M., Maynard, J.E., and Bradley, D.W. (1983) Unrelatedness of Factor VIII Derived NonA/NonB Hepatitis and Hepatitis B Virus. J. Med. Virol. 11: 59-65.

Deen, K.C., Landers, T.A., and Berninger, M. (1983) Use of T4 DNA Polymerase Replacement Synthesis for Specific Labeling of Plasmid-Cloned Inserts. Anal. Biochem. 135: 456-465.

Negro, F., Berninger M., Chiaberge, E., Gugliotta, P., Bussolati, G., Actis, G.C., Rizzetto, M., and Bonino, F. (1985) Detection of HBV-DNA by In Situ Hybridization Using Biotin-Labeled Probe. *J. Med Virol.* 15: 373-382

Hartley, J.L., Berninger, M., Jessee, J.A., Bloom, F.R., and Temple, G.F. (1986) Bioassay for Specific DNA Sequences Using a Non-Radioactive Probe. *Gene* 49: 295-302

Longo, M.C., Berninger, M., and Hartley, J.L. (1990) Use of Uracil DNA Glycosylase to Control Carry-Over Contamination in Polymerase Chain Reactions. *Gene* 93: 125-128.

Rashtchian, A., Buchman, G.W., Schuster, D.M., and Berninger M. (1992) Uracil DNA Glycosylase-Mediated Cloning of Polymerase Chain Reaction-Amplified DNA: Application to Genomic and cDNA Cloning. *Anal. Biochem.* 206:91-97.

U.S. Patents: (Inventor or Co-inventor)

- 4,446,237 Method for the Detection of a Suspect Viral Deoxyribonucleic Acid in an Acellular Biological Fluid.
- 4,808,519 Method for Detecting Nucleic Acid Sequences.
- 4,830,725 Electrophoresis Apparatus.
- 4,889,610 Pop-up Electrophoresis Apparatus and Method.
- 315,951 Reaction Tank for Electrophoresis Apparatus. (Design Patent)
- 315,952 Horizontal Gel Electrophoresis Unit. (Design Patent)
- 5,106,727 Amplification of Nucleic Acid Sequences Using Oligonucleotides of Random Sequence as Primers
- 5,137,814 Use of Exo-Sample Nucleotides in Gene Cloning.
- 5,169,766 Amplification of Nucleic Acid Molecules.
- 5,194,370 Promoter Ligation Activated Transcription Amplification of Nucleic Acid Sequences
- 5,229,283 Use of Exo-Sample Nucleotides in Gene Cloning (cont. of US Patent 5,137,814)
- 5,683,896 Process for Controlling Contamination of Nucleic Acid Amplification Reactions